IN THE HIGH COURT OF JUDICATURE AT PATNA

Civil Writ Jurisdiction Case No.14573 of 2021

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Shashi Ranjan Singh Son of Sri Binod Prasad Singh Resident of Office of Nagar Nigam Senapat, P.O. and P.S. - Darbhanga (Town), District- Darbhanga (Bihar) Presently Residing at ASMI Apartment, 1st Floor, Haripur Colony, P.O. - Digha Ghat, P.S. - Digha, District- Patna, Pin Code - 800011 (Bihar).

... ... Petitioner/s

Versus

1. The State of Bihar through the Chief Secretary, Government of Bihar, Old Secretariat, Patna.
2. The Chief Secretary, Government of Bihar, Old Secretariat, Patna.
3. The Additional Secretary, Health Department, Government of Bihar, Patna.
4. The Joint Secretary, Health Department Section - 15, Government of Bihar, Patna.
5. The Drugs Controller, Department of Health, Government of Bihar, Patna.
6. Sri Ravindra Kumar Sinha, In - Charge Drugs Controller, Department of Health, Government of Bihar, Patna.
7. Smt. Shivani, Assistant Drugs Controller, Muzaffarpur as the the was, Presently posted as Assistant Drugs Controller, West Champaran at Bettiah.
8. The Union of India through the Durgs Directorate General of Health Services, Union of India, F.D.A. Bhawan, Kotla road, New Delhi - 110002.
9. The Drugs Controller General of India, Office of the Directorate General of Health Services, Union of India, F.D.A. Bhawan, Kotla Road, New Delhi - 110002.

... ... Respondent/s

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Appearance :
For the Petitioner/s : Mr.Shri Prakash Srivastava, Advocate
For the Respondent/s : Mr.S.D. Yadav (AAG-9)

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CORAM: HONOURABLE THE CHIEF JUSTICE
and
HONOURABLE MR. JUSTICE PARTHA SARTHY
CAV JUDGMENT

(Per: HONOURABLE THE CHIEF JUSTICE)

Date : 17 -08 -2023

The petitioner has filed the instant Public Interest

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Litigation seeking appropriate action against the persons who indulge in illegal trade of banned medicines, with the aid and help purportedly of the 5th respondent, in which office the 6th respondent is the incumbent. The petitioner also seeks a mandamus commanding the 8th respondent to place on record the instances where the power conferred under Section 26 (A) of the Drugs and Cosmetics Act, 1940 (for brevity "DCA") has been carried out, especially in the State of Bihar wherein Respondent No. 6 is said to be actively perpetuating the illegal trade of medicines by manufacturers who change the composition slightly to escape from the ban imposed. The petitioner also seeks an enquiry by Central Bureau of Investigation (C.B.I) into the illegal trade of banned medicines. We cannot, but say that the prayers are quite ambitious, especially considering the meager facts placed before us in support of the allegations.

2. The petitioner contends in the writ petition that the 8th respondent has issued a gazette notification listing out 344 hazardous and dangerous medicines; in violation of which rampant sale of banned drugs are being carried out within the State of Bihar with the active connivance of the 6th respondent who is in-charge of the post of Drugs Controller in the State.

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The petitioner also submits that the 7th respondent, who is the Assistant Drugs Controller has sent letter dated 12.06.2021 for taking action against the banned drugs and unapproved Fixed Dose Combination (for brevity "FDC") medicines. The letter of the 7th respondent is produced as Annexure-1. It is also stated that a Drugs Inspector had sent an e-mail message to the 9th respondent, specifically pointing out the failure of the system in taking action against the concerned pharmaceutical companies, in response to which the 9th respondent sent a letter dated 11.02.2021 seeking information as to the steps taken by the office of the 5th respondent. Despite frequent reminders to the 5th respondent by Annexure-3 and Annexure-4, there is no response from the 5th respondent to the 9th respondent. A representation by the petitioner was also submitted before the 3rd respondent dated 14.06.2021, which is produced as Annexure-5.

3. The petitioner's contention is that the composition of the banned medicines are changed slightly with the connivance of manufacturers and suppliers, thus putting on sale medicines which are hazardous and injurious to life to the public at large. The petitioner has also spoken about a ban imposed on the combination of Azithromycin + Cefixime, which is sought to be avoided by including Lactic Acid Bacillus. The petitioner

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also names a medical shop within which premises the said tablets were found, in which packets were endorsed the name of the manufacturer and supplier; extracted in the memorandum. On Page 16, three establishments who are said to be manufacturer/marketeers are styled as habitual offenders. The petitioner has also spoken of certain specific medicines in Paragraph 18 and 19 of the writ petition, which also is said to be in the market with a slight change of composition, to escape the ban imposed. We cannot, but notice that none of the pharmaceutical companies or the marketing companies or even the medical shop referred to in the writ petition are made parties herein. In Annexure- P1, there is a long list of agencies involved in the pharmaceutical business, who too have not been impleaded in the present case.

4. Be that as it may, the writ petition was filed as early as in 2021 and there were orders passed directing affidavits to be filed which has been done on various occasions. Respondent Nos. 8 and 9 have filed an affidavit dated 06.10.2021, detailing the provisions under the DCA and also the responsibilities of the respective regulatory departments under the State and the Centre. Communications are produced, by which due caution is directed on the State Authorities to instruct

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their licensing authorities to refrain from granting licenses for manufacture of 'new drugs' without due approval from the Drugs Controller General (India) (Annexure-R1) and the State and Union Territory Drugs Controllers to ensure that the manufacturers comply with safety and efficacy of FDCs, falling under the term of 'new drugs' (Annexure-R2). An expert committee constituted by the Ministry of Health and Family Welfare submitted Annexure-R3 report, which has categorised the FDCs. The Central Government under Section 26 (A) of the DCA has prohibited the manufacture for sale, sale and distribution for human use of 344 drugs of FDC by gazette notification Bearing No. S.O 705 (E) to 1048(E) dated 10.03.2016.

5. However, the said notification was quashed by the Hon'ble High Court of Delhi vide its order dated 01.12.2016. There are also writ petitions filed in the various High Courts. Insofar as the communications received from the State of Bihar, specific directions were issued to the State Licensing Authority to take action as per the requirements and for transmitting an action taken report by the concerned officer.

6. Respondents 3 to 5 have filed a counter affidavit in the year 2021 and the 3rd respondent in the year 2022. We have

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perused the counter affidavit filed by the 3rd respondent who is the Additional Chief Secretary, Health Department, Patna, which contains the updated factual status of the issue agitated in the writ petition. It is stated that the Health Department of Bihar is carrying out supervision and monitoring of trade in medicines and there is every step taken to stop illegal trade of unapproved/banned drugs. The responsibilities of the State Government under the DCA, the Rules framed thereunder and the New Drugs and Clinical Trials Rules, 2019 have been listed out. This involves licensing of manufacturing establishments, units and sale premises, inspection of the license, taking of samples for testing and monitoring the quality, suspension/ cancellation of license, surveillance over sale of spurious drugs and instituting legal action wherever required under the Act and the Rules.

7. The State Drugs Controller is asserted to be carrying out such duties, through the Assistant Drug Controllers and Drugs Inspectors. The issue of FDCs had been under controversy in the various States, the manufacture of which has to be with permission from the Drugs Controller General of India and the Central Drugs Standard Control Organisation; which is an essential requirement for obtaining manufacturing

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license from the State Licensing Authority. It is also pointed out by the State Authority that the various notifications prohibiting drugs have been under challenge before the various Courts and even the Hon'ble Supreme Court. There were also instances of banned FDC formulations being later approved by the Ministry of Health and Family Welfare.

8. It is also stated that the supervision and monitoring of the State Government over the manufacturers and sale of FDC drugs is a complex and continuous phenomenon requiring constant vigilance together with punitive action which is taken by the State Drug Control Administration, Government of Bihar. The several remedial measures to tighten control over misuse of FDC in Bihar has been listed out as follows:-

> *(A) Health Department, Govt. of Bihar vide Departmental Order no. 410 (15) dated 16.04.2019 has constituted Vigilance Cell both at the the District level and State level to ensure compliance of the guidelines issued by the Ministry of Health and Family Welfare, Govt. of India from time to time with respect to FDC/Banned drugs and simultaneously, the said Vigilance Committee shall ensure that no license be issued for new drugs without prior approval of Drugs Controller General of India and monitor manufacturing, sale and Distribution of prohibited drugs. (Annexure-B)*
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> *(B) Sanction of prosecution against the guilty persons/ institutions regarding manufacturing, sale*

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and distribution of unapproved fixed dose Combination drugs/banned drugs and others, the State Drug Controller, Bihar, Patna in the light of recommendation made by the Departmental Prosecution Screening Committee and after through consideration of the available evidence and completion of formalities, has given approval for prosecution under Rule 74, 80 and 83 of the NDCT Rules, 2019 and other sections and Rules of the Drugs and Cosmetics Act, 1940 and rules 1945. In this regard, a large number of sanctions for 270 through various letters of State Drug Controller, Bihar have been issued. (Annexure-C).

(C) Directorate of State Drugs Control Administration, Bihar, Patna has been constantly issuing reminder thereby directing all the Assistant Drugs Controllers and Drug Inspectors of Bihar to take appropriate action against as unapproved/banned FDC drugs and seek prosecution from the competent authority promptly and further to supervise and investigate as per the provisions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 at their own level and immediate seek prosecution from Directorate Drugs Control Administration, Health Department, Bihar and such reminder letters. (Annexure-D).

(D) In pursuance to above the Drug Inspectors at District level have submitted reports with respect to unapproved FDC drugs and in the light of the provisions contained in section 22 (1) (d) of Drugs and Cosmetics Act, 1940 have also issued stay order on sale, purchase, distribution and circulation of

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such FDC drugs. In this regard, the State Drugs Controller vide Departmental Letter No. 1715 (15) dated 20.12.2019 sought guidelines from the Drugs Controller Gencral of India as to what further action is required to be taken against the manufacturer, marketing and sale establishments of such unapproved FDC drugs. (Annexure-E)

(E) Thereafter, the State Drugs Controller, Bihar, Patna vide his letter no. 05 (15) dated 03.01.2020 again sent reminder letter to the Drugs Controller General of India seeking guidelines in the matter of taking suitable action against the manufacturer and seller of unapproved FDC drugs. (Annexure-F)

(F) Thereafter, the State Drug Controller, Bihar vide his various Letters issued show cause notice against various institutions/ concerned persons for producing necessary documents with respect to the unapproved FDC drugs. It is relevant to mention here that those FDCs are not approved by Bihar Drugs Control Administration, Patna. (Annexure-G)

(G) Thereafter, the State Drugs Controller, Bihar, Patna vide his letter no. 143 (15) dated 31.01.2020 again sent reminder to the Drugs Controller General of India requesting him to send guidelines on the matter of taking action against the manufacturer and seller firms of unapproved FDC drugs. A reminder letter bearing Memo NO. 414 (15) dated 27.03.2020 was also sent by the State Drug Controller, Bihar to the Drugs Controller General of India in this regard. (Annexure-H and H/1)

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(H) The Drugs Controller General of India vide his letter dated 18.09.2020 informed and enclosed a detailed status in respect of each FDC Drugs. (Annexure-I)

(I) State Drugs Controller, Bihar, Patna vide his various letters has also requested to the various State Drugs Controller cum Licensing Authority of different states of India to take appropriate action in accordance with law with respect to manufacturer of unapproved FDC drugs falling under their jurisdiction. (Annexure-J)

(J) Thereafter, the Drugs Controller General of India vide his letter dated 11.02.2021 and 22.02.2021 addressed to the State Drugs Controller, Bihar informed on the matter of unapproved FDC of Cefixime Trihydrate + Azithromycin + Lactic Acid Bacillus tablets and unapproved FDC of Nimesulide BP 100 mg + Phenylepherine HCL IP 10 mg + Cetirizine Dihydrochloride IP 5 mg + Caffeine Anhydrous IP 30 mg uncoated tablets not approved by Bihar Drugs Control of Administration. The Central Government through Gazette Notification has prohibited FDC of Azithromycin + Cefixime vide S.O. 4422 (E) dated 07.9.2018. However, FDC in question is a FDC OF Azithromycin + Cefixime + Lactic acid Bacillus is not approved by CDSCO & Bihar Drugs Control Administration. (Annexure-K)

(K) With regard to other FDC drugs mention in the petition i.e. FDC of Nimesulide + Phenylepherine Hydrochloride + Cetirizine hydrochloride + Caffeine Anhydrous tablet, in this regard, it is submitted that this FDC is not approved by CDSCO

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& Drugs Control Administration of Bihar.

(L) Thereafter, the State Drugs Controller, Bihar vide his letter no. 476 (15) dated 18.03.2021 and letter no. 584 (15) dated 13.04.2021 addressed to the Drug Inspector, Muzaffarpur -2 and Muzaffarpur -1 communicated the sanction order for prosecution against the concerned persons with respect to aforementioned unapproved FDC. (Annexure-L and L/1)

(M) In the meantime, with reference to letter dated 01.07.2021 of Drugs Controller General of India regarding unapproved FDC Drugs in the light of the report of the Drugs Inspector, Muzaffarpur -2, the State Drugs Controller, Bihar vide his letter no. 939 (15) dated 13.07.2021 has informed the Drugs Controller General of India regarding the actions taken in this matter. (Annexure-M)

9. Considering the averments in the counter affidavits filed and also looking at the complexity involved in supervision and monitoring the manufacture and sale of FDCs, especially in the context of the sketchy averments made in the writ petition, we are of the opinion that the matter need not be kept pending. We only caution the various respondent authorities to be vigilant, especially considering the complexity of the issue and the gravity of the deleterious effects of sale of such banned medicines to the public at large.

10. The writ petition would stand disposed of with the

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above observations.

(K. Vinod Chandran, CJ)

Parth Sarthy, J I agree

(Partha Sarthy, J)

Anushka/-

AFR/NAFR	
CAV DATE	08.08.2023
Uploading Date	17.08.2023
Transmission Date	

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